FEB - 9 2004

7998 Georgetown Rd
Suite 1000
Indianapolis, IN 46268

510K SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K033674

1. COMPANY/CONTACT PERSON:

Seradyn, Inc
7998 Georgetown Road,
Suite 1000
Indianapolis, IN 46268

Establishment registration No: 1836010

Les Padilla
Technical Product Manager
Telephone: (317) 610-3823
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2. DATE PREPARED: November 18, 2003

3. DEVICE NAME:

a. Proprietary Name:	MULTIGENT™ Hemoglobin A1c Reagents MULTIGENT™ Hb A1c Calibrators MULTIGENT™ Hb A1c Controls
b. Common Name:	Hemoglobin A1c (Hb A1c); Glycated / Glycosylated Hemoglobin
c. Classification Name:	Class II, LCP, 21 CFR 864.7470 Glycosylated Hemoglobin assay

4. LEGALLY MARKETED DEVICES TO WHICH EQUIVALENCY IS CLAIMED:

Tosoh Medics Inc., G7 Automated HPLC Analyzer: HbA1c Variant Analysis Mode, cleared under K011434.

5. DESCRIPTION OF DEVICE:

The Device consists of the MULTIGENT™ Hemoglobin A1c Reagents, MULTIGENT™ Hemoglobin A1c Calibrators , and MULTIGENT™ Hemoglobin A1c Controls, intended for use on AEROSET® System and ARCHITECT® *c*8000™ System for determination of stable % HbA1c.

The assay consists of two separate concentration measurements, the stable form of glycated hemoglobin (Hb A1c) and the total hemoglobin (THb), which are used only to determine the percent Hb A1c. and *must not* be used individually for diagnostic purposes.

The whole blood specimen is pre-treated to lyse the erythrocytes. The hemoglobin is degraded by the proteolytic enzyme, pepsin, to form a hemolysate. Both the THb and the Hb A1c concentrations are determined from the same hemolysate.

The concentration of total hemoglobin is determined colorimetrically using a wavelength of 604 nm. The sample's measured absorbance is compared to a two-point calibration curve for total hemoglobin.

The concentration of stable Hb A1c is measured immunoturbidimetrically using a microparticle agglutination inhibition method. The Hb A1c antibody reagent (R1) contains specific anti-Hb A1c mouse monoclonal antibodies coupled to microparticles. The Hb A1c agglutinator reagent (R2) contains several copies of the immunoreactive portion of Hb A1c (hapten), covalently bound to a polymer.

In the absence of Hb A1c in the sample, the hapten in the R2 reagent binds with the antibody-coated microparticles in the R1 antibody reagent and results in an increase in the rate of agglutination and results in an increase in measured absorbance. In the presence of Hb A1c in the sample, the Hb A1c competes with the hapten in the R2 reagent for binding sites on the antibody-coated microparticles in the R1 antibody reagent and will slow the rate of agglutination as it competes with the Hb A1c agglutinator for antibody binding sites.

The increase in concentration of Hb A1c in the sample is inversely proportional to the rate of agglutination and the measured absorbance. The absorbance is measured using a wavelength of 700 nm. The measured absorbance of the sample is compared to the measured absorbance of known Hb A1c concentrations (g/dL) of a six-level calibration curve, and the concentration of the sample is interpolated. The percent Hb A1c is the Hb A1c /THb ratio, calculated automatically by the AEROSET® System and ARCHITECT® *c*8000™ System, using a conversion factor to correlate the result with an NGSP-certified method.

The calibrators are supplied in liquid form and are ready to use without pretreatment. The controls are supplied in lyophilized form and are to be reconstituted with the supplied reconstitution fluid.

6. INTENDED USE:

The MULTIGENT™ Hb A1c assay is used in clinical laboratories for the quantitative *in vitro* measurement of percent Hb A1c (hemoglobin fraction) in human whole blood on the AEROSET® System and ARCHITECT® *c*8000™ System. The Hb A1c assay is intended to aid in the monitoring of long-term blood glucose control and compliance in individuals with diabetes mellitus. The MULTIGENT™ Hb A1c assay is not intended for use in diagnosing diabetes mellitus.

The MULTIGENT™ Hb A1c Calibrators are intended for *in vitro* diagnostic use with the AEROSET® System and the ARCHITECT® *c*8000™ System for the calibration of the assays in the MULTIGENT™ Hb A1c Reagent Kit.

The MULTIGENT™ Hb A1c Controls are intended for *in vitro* diagnostic use with the AEROSET® System and the ARCHITECT® *c*8000™ System for quality control of the assays in the MULTIGENT™ Hb A1c Reagent Kit.

7. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS:

The MULTIGENT™ Hemoglobin A1c system for measuring % Hb A1c is based on an immunoturbidimetrically microparticle agglutination inhibition method that is specific for stable Hb A1c and is used in conjunction with a colorimetric method to determine the Total Hemoglobin.

The Predicate device, Tosoh Medics Inc., G7 Automated HPLC Analyzer: Hb A1c Variant Analysis Mode, uses an automated High Performance Liquid Chromatography (HPLC) system, a cation exchange column and gradient elution buffers which separates the stable Hb A1c from other hemoglobin components

Although the MULTIGENT™ Hemoglobin A1c system has technological differences from the predicate device, the intended use are similar and the results from performance characteristics data from non-clinical studies supports a claim of substantial equivalence to the predicate device.

The performance data is summarized below.

8. SUMMARY OF NON-CLINICAL TESTING (COMPARATIVE ANALYSIS TO PREDICATE DEVICE LABEL CLAIMS:

Linearity (% HbA1c) and Limit of Detection

Linearity of the MULTIGENT™ HbA1c assay for the reportable % Hb A1c is from 2% to 20%. The label claim for the predicate device is 4.2% to 20.8%

Specificity and Interfering Substances:

The MULTIGENT™ Hb A1c assay has no interference as defined by acceptance criteria of difference of ≤ 1% Hb A1c when compared to an untreated sample. Below is a summary of the concentrations tested with the MULTIGENT™ HbA1c assay and the predicate device. Tosoh acceptance criteria is ± 10% of the untreated sample.

Interfering Substance	Concentrations of Interferent Tested by MULTIGENT™ Hb A1c Assay with	Concentrations of Interferent Tested By TOSOH G7 Automated HPLC
Bilirubin	50 mg/dL	20 mg/dL
Triglyceride	1600 mg/dL	2000 mg/dL
Rheumatoid Factor	3100 U/mL	None reported
Acetyl Salicylate	50.8 mg/dL	None reported
Sodium Cyanate	50 mg/dL	20 mg/dL
Ascorbic Acid	50 mg/dL	None reported
Urea (Carbamyl GHb)	667 mg/dL	None reported
Gamma Globulin	5 g/dL	None reported
HAMA Type 1	Plasma 100% replaced	None reported
HAMA Type 2	Plasma 100% replaced	None reported
Labile Hb A1c	14 mg/mL of glucose	Separates LA1c
A1a	2.85 %	Chromatographically Separates out A1a
A1b	1.25%	Chromatographically Separates out A1b

Precision

Precision studies for the MULTIGENT™ Hemoglobin A1c assay was performed on both the AEROSET® System and ARCHITECT® *c*8000™ System using the NCCLS EP5-A protocol (n=80). The studies demonstrated that a whole blood sample with a mean of approximately 5.0% HbA1c, a within run precision of 1.17 % CV, a between run precision of 0.40 %CV, and a total precision of 1.46 %CV was achieved. For a whole blood sample with approximately 10.5% HbA1c, a within run precision of 1.07 % CV, a between run precision of 0.73 %CV, and a total precision of 1.31 %CV was achieved.

The predicate device precision labeling claims are: within run precision of 0.90 %CV, between run precision of 0.40%CV, and a total precision of 1.12 %CV for a whole blood sample with a mean of 5.8% HbA1c. A whole blood sample with a mean of 10.9% HbA1c had a within run precision of 0.53 %CV, between run precision of 0.46%CV, and a total precision of 0.71 %CV

The precision of the MULTIGENT™ Hemoglobin A1c assay, performed on either the AEROSET® System and ARCHITECT® *c*8000™ System are within acceptable limits. None of the raw data values differed from a MIN/MAX of >1% Hb A1c.

Method Comparison

Correlation studies were performed by assaying whole blood patient samples on the Abbott AEROSET® System and the Abbott *c*8000 system using the MULTIGENT™ Hb A1c assay and the Tosoh G7 Automated HPLC – Hb A1c Variant Analysis Mode. The data was subjected to linear regression statistics (least squares method) and yielded the following results:

Regression Statistics		
Independent Variable	Tosoh	Tosoh
Dependent Variable	Aeroset	c8000
Multiple R (Corr. Coef.)	0.993	0.994
Observations (n)	117	117
y-Intercept	0.240	0.141
Slope	0.976	0.998

9. CONCLUSIONS:

The results of non-clinical testing demonstrate that the performance and safety and effectiveness of the MULTIGENT™ Hb A1c assay on the Abbott AEROSET® System and the Abbott ARCHITECT® *c*8000 system are substantially equivalent to that of the Tosoh G7 Automated HPLC – Hb A1c Variant Analysis Mode.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB - 9 2004

Mr. Les Padilla
Technical Product Manager
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7998 Georgetown Road – Suite 1000
Indianapolis, IN 46268-5620

Re: k033674
Trade/Device Name: Multigent™ Hemoglobin A1c on the Abbott Aeroset® System and the Abbott Architect® c8000™ System
Regulation Number: 21 CFR 864.7470
Regulation Name: Glycosylated hemoglobin assay
Regulatory Class: Class II
Product Code: LCP; GGM; KRZ
Dated: November 19, 2003
Received: November 24, 2003

Dear Mr. Padilla:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
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Enclosure

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INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K033674

Device Name: **MULTIGENT™ HEMOGLOBIN A1c ON THE ABBOTT AEROSET® SYSTEM AND THE ABBOTT ARCHITECT® *c*8000™ SYSTEM**

Indications For Use:

The MULTIGENT™ Hb A1c assay is used in clinical laboratories for the quantitative *in vitro* measurement of percent Hb A1c (hemoglobin fraction) in human whole blood on the AEROSET® System and ARCHITECT® *c*8000™ System. The Hb A1c assay is intended to aid in the monitoring of long-term blood glucose control and compliance in individuals with diabetes mellitus. The MULTIGENT™ Hb A1c assay is not intended for use in diagnosing diabetes mellitus.

The MULTIGENT™ Hb A1c Calibrators are intended for *in vitro* diagnostic use with the AEROSET® System and the ARCHITECT® *c*8000™ System for the calibration of the assays in the MULTIGENT™ Hb A1c Reagent Kit.

The MULTIGENT™ Hb A1c Controls are intended for *in vitro* diagnostic use with the AEROSET® System and the ARCHITECT® *c*8000™ System for quality control of the assays in the MULTIGENT™ Hb A1c Reagent Kit.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Carol C Benson
Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K033674